IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

ALLERGAN, INC. *Plaintiff,* v. TEVA PHARMACEUTICALS USA, INC., et al., *Defendants.*	§ § § § § § § § § §	Case No. 2:15-CV-1455-WCB

MEMORANDUM OPINION AND ORDER

Before the Court are the parties' submissions regarding the declaratory judgment claims under 35 U.S.C. § 271(a), (b), and (c), Dkt. Nos. 405 and 406, and regarding the request of plaintiff Allergan, Inc., for notice before any at-risk launch by any defendant, Dkt. Nos. 407 and 408. After consideration of the briefs filed by the parties, the Court will not at this time order the defendants to give Allergan seven days' advance notice of any at-risk launch. As for the declaratory judgment claims, the Court will not dismiss or sever those claims, but will retain them as part of the case to be tried.

Also before the Court is the defendants' Notice of Stipulation of Infringement and Motion to Modify the Order of Proof at Trial, Dkt. No. 415, and Allergan's Brief in Response to Defendants' Notice of Stipulation of Infringement and Motion to Modify the Order of Proof at Trial, Dkt. No. 433. While the defendants are free to concede or not contest any particular issue at trial, the proposed stipulation does not, in the Court's view, take the issue of infringement out of the case and does not warrant changing the order of proof at trial. The motion to modify the Order of Proof at Trial is therefore DENIED.

1. Advance Notice of At-Risk Launch.

Arguing that it would face irreparable harm if any of the defendants launch a generic version of Allergan's Restasis product during the pendency of this litigation, Allergan requests that the Court order the defendants to provide Allergan with seven days' advance notice of any plan to launch such a product. The defendants object, arguing that the Court lacks authority to issue such an order, that Allergan's request for such an order is unripe, that Allergan has not made a showing of irreparable harm that would justify such an order, and that such an order would harm them competitively.

None of the defendants is free at this point to launch their generic versions of Restasis, because the federal Food and Drug Administration has not yet approved any of their Abbreviated New Drug Applications ("ANDAs"). However, the parties have advised the Court that the FDA is expected to act on at least some of the defendants' ANDAs shortly. Allergan notes that it is at least open to question whether the 30-month stay that normally applies to generic manufacturers in Hatch-Waxman litigation would apply to several of the defendants in this case. Therefore, according to Allergan, there is a substantial risk that those defendants might conduct an at-risk launch before the expiration of the 30-month period.

Four of the five defendants—Akorn, InnoPharma, Mylan, and Teva—have advised the Court that they have agreed not to launch before the trial is complete. The remaining defendant, Famy Care Ltd., is subject to a 30-month stay of approval and therefore is not free to launch before the time that this Court is likely to enter its judgment in this case. See Dkt. No. 407, at 2 & n.1.

The defendants argue that the Court lacks the authority to enter an order requiring them to provide Allergan with seven days' notice of their intent to launch. There is very little

authority on this point, and what authority there is shows up mainly in the form of terse observations by district courts without extended analysis. A few courts have issued such orders, often when they are agreed to, at least in part. See, e.g., Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A. v. Actavis S. Atl. LLC, No. 1:12-cv-1061, Dkt. No. 21 (D. Del. Jan. 9, 2013); Medeva Pharma Suisee A.G. v. Roxane Labs, Inc., No. 3:07-cv-5165, Dkt. No. 119, at 1 (D.N.J. Nov. 30, 2009); Eli Lilly & Co. v. Sicor Pharms., Inc., Case No. 1:06-cv-238, Dkt. No. 171 (S.D. Ind. June 20, 2008).

A greater number of courts have refused to issue such orders, often expressing doubt as to their authority to do so. See Otsuka Pharm. Co. v. Torrent Pharms. Ltd., 99 F. Supp. 3d 461, 471-72 (D.N.J. 2015) (recognizing "the principle that the generic defendants would not be required to provide notice of intent to launch at risk"); Hoffman-LaRoche, Inc. v. Teva Pharms. USA, Inc., No. 2:11-cv-3635, Dkt. No. 124 (Feb. 5, 2013) ("[T]he Court is not persuaded by Roche's arguments that the Court has the authority to order advance notice of its intent to launch in the absence of an agreement by Teva."); Teva Pharms. USA, Inc. v. Sandoz, Inc., No. 08 Civ. 7611, 2010 WL 8760315, at *1 (S.D.N.Y. Oct. 12, 2010) ("Plaintiff's request amounts, in essence, for the Court to order Defendants to provide Plaintiffs with confidential business information, which for all intent and purposes, would function as an injunction by prohibiting Defendants from launching their product even if they have FDA approval and the thirty-month statutory stay period has expired."); Astrazeneca LP v. Breath Ltd., No. 08-cv-1512, Dkt. No. 86, at 2 (D.N.J. Sept. 8, 2009) (request for order to provide advance notice of launch "is denied for the reasons set forth in the record of these proceedings, including because the Court does not believe it has legal authority to grant such relief."); Novartis Pharms. Corp. v. Mylan Pharms., No. 3:06-cv-2885, Dkt. No. 98, at 6 (D.N.J. Sept. 22, 2008) ("I've been reluctant and have

refused to require that Mylan state when they would launch . . . [b]ecause frankly I am not comfortable in determining that that is within my power to do.").

Allergan asserts that entering such an order is within the Court's discretionary power to manage its docket. The Court is not persuaded that the matter is that simple. Imposing an obligation on four of the five the defendants to provide advance notice to Allergan as to when they will launch their competing products goes well beyond a mere matter of docket control; as recognized by Judge Jones in the Teva v. Sandoz case cited above, it constitutes an injunction that can be justified if and only if (1) the court has jurisdiction to issue the injunction and (2) the court has made the requisite findings to warrant imposing such relief.

As to the first, the Court is satisfied that, under the proper circumstances, an order to provide advance notice of a planned launch would not lie beyond the Court's jurisdiction. The Court's equitable powers in a case such as this one extend to ancillary orders that may be necessary to protect the protect the plaintiff against the risk that the defendants will take action that will effectively defeat the plaintiff's right to relief.

While recognizing that the Court's jurisdiction may extend to matters such as orders for advance notice of launch plans, the Court is cognizant of the prudential limitations on the exercise of that jurisdiction. Launch dates are highly confidential and important commercial information. The Court should not lightly order parties to disclose such information to their competitors. Moreover, before entering such a mandatory injunction, the Court would have to be confident that the equitable considerations that govern the issuance of injunctions require the grant of the requested relief. At this point, the Court is not satisfied that those equitable considerations justify the entry of the requested injunction, for several reasons.

First, the Court is not currently prepared to conclude that Allergan has shown a likelihood of success on the merits that would warrant the requested relief. The Court is aware at this point only of the outlines of the parties' cases. After sitting through the trial, the Court will have a much better sense of Allergan's likelihood of success, which will bear importantly on how the Court will adjudicate Allergan's various claims to temporary and permanent relief thereafter.

Second, the defendants have agreed not to launch their generic versions of Restasis during the trial. There is therefore no urgency for the Court to act prior to trial. Instead, the Court will be able to reassess the need, if any, for the requested injunctive relief after hearing the evidence in the case.

Third, Allergan's claim of irreparable harm is predicated on an affidavit by one of its employees and some citations to court decisions. Dkt. No. 408-1. Allergan's claim is disputed by the defendants, who contend that Allergan's assertions regarding the damage that any at-risk launch would cause to Allergan is greatly exaggerated. Dkt. No. 407, at 5-6. If Allergan continues to desire some form of interim relief, it can move for a preliminary injunction and, in support of that motion, can offer evidence regarding the injury that would be caused by an at-risk launch. The defendants will be free at that point to offer contrary evidence if they choose. The parties can also present evidence and argument regarding whether the harm to Allergan from an at-risk launch would be compensable in damages, assuming Allergan were ultimately to prevail in the lawsuit. That procedure will likely provide the Court with a much sounder evidentiary basis for making a determination as to whether Allergan has shown irreparable harm.

For now, the Court sees no need to issue an order directing the defendants to give Allergan seven days' notice of their intent to launch; that issue can be revisited at trial, when the issues bearing on Allergan's entitlement to any such relief will presumably be clearer.

2. The Disposition of Allergan's Claims Under 35 U.S.C. § 271(a), (b), and (c).

In its complaint, Allergan has not only brought claims for infringement under the Hatch-Waxman Act infringement provision, 35 U.S.C. § 271(e)(2), but also has sought a declaratory judgment that any launch by the defendants would result in infringement under the more conventional direct and indirect infringement statutes, 35 U.S.C. § 271(a), (b), and (c).[1] Because the Court was concerned that the proof for the latter claims would complicate the case unnecessarily, the Court asked the parties to brief the question whether the declaratory judgment claims should be severed, or dismissed without prejudice, while the Hatch-Waxman claims were tried. The defendants requested that the Court sever the declaratory judgment claims; Allergan requested that the Court not sever or dismiss those claims, but try them alongside the section 271(e)(2) claims.

Allergan has put to rest the Court's principal concern regarding the section 271(a), (b), and (c) claims by representing to the Court that the evidence in support of those claims will be the same as the evidence in support of the section 271(e)(2) claims, and that the judgment on the section 271(e)(2) claims will also resolve the declaratory judgment claims. Dkt. No. 405, at 1. Therefore it makes sense to retain those claims as part of the case to be tried along with the section 271(e)(2) claims.

[1] In this setting, where it is clear that the defendants intend to sell their generic products if they prevail in this section 271(e)(2) action, the Court has jurisdiction to address Allergan's declaratory judgment claim brought under sections 271(a), (b), and (c). See Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1570-71 (Fed. Cir. 1997); Cephalon, Inc. v. Watson Pharms., Inc., 629 F. Supp. 2d 338, 351 (D. Del. 2009).

As a practical matter, the difference between severing the claims and retaining all the pending claims in the same case may not be significant. However, it may be useful to facilitate the consideration of the section 271(a), (b), and (c) claims along with the 271(e)(2) claims, if that appears advisable in the course of the proceedings rather than having the two sets of claims segregated for purposes of trial. Accordingly, the Court will retain the section 271(a), (b), and (c) claims as part of the case to be tried and will neither dismiss nor sever those claims.

3. The Defendants' Notice of Stipulation of Infringement and Motion to Modify the Order of Proof at Trial.

On August 18, 2017, the defendants filed a "notice of stipulation" in which they stated that they "do not intend to dispute at trial infringement under § 271(e)(2) under the present claim construction" of the claims that are before the Court for trial. Dkt. No. 415, at 1. They also moved to change the order of proof at trial, so that the order of proof would "begin with the Defendants' case on invalidity, then proceed to Allergan's rebuttal of validity, and end with Defendants' reply." Dkt. No. 415, at 2.

Allergan has objected to the defendants' proposal on several grounds. Dkt. No. 433. First, Allergan has scheduled several third-party witnesses to appear on the first day of trial, and modifying the order of proof would significantly inconvenience them. Second, Allergan objects to the qualifications attached to the defendants' stipulation as to infringement—both that it is limited to conceding infringement "under the present claim construction," and that it is limited to conceding infringement under 35 U.S.C. § 271(e)(2), and not necessarily under 35 U.S.C. § 271(a), (b), and (c), which are also pleaded in Allergan's complaint. Allergan also expresses concern that the stipulation might not have preclusive effect in later proceedings.

The Court shares Allergan's reservations about the defendants' proposed stipulation. For one thing, as the Court explained in its order denying the defendants' motion for invalidity based

on lack of enablement, Dkt. No. 393, the Court anticipates that in light of the parties' positions as revealed in the brief of that motion, it will likely be necessary to construe the term "acrylate/C10-30 alkyl acrylate cross-polymer" at trial, and that the Court expects the parties to provide additional evidence on that issue at trial. Because that issue bears on infringement as well as invalidity, the defendants' stipulation to infringement under the "the present claim construction" is no real stipulation at all.[2]

The defendants are free to stipulate to particular facts or legal issues at trial, which could have the desired effect of shortening the proceedings. In addition, the defendants are free not to challenge Allergan's proof of infringement if they so choose, which presumably would also have the effect of shortening the trial. But in the particular circumstances of this case, the Court is wary of accepting a stipulation conditioned on the claim construction being correct.[3] That is not to cast doubt on either (1) the frequent practice of parties that enter an unconditional stipulation to infringement in order to contest validity, see, e.g., Millennium Pharms., Inc. v. Sandoz, Inc., 862 F.3d 1356 (Fed. Cir. 2017); Cumberland Pharms Inc. v. Mylan Institutional LLC, 846 F.3d 1213 (Fed. Cir. 2017); Merck & Cie v. Watson Labs., Inc., 822 F.3d 1347 (Fed. Cir. 2016), or (2) the occasional practice, by a party who has received an unfavorable claim construction, of

[2] In its order denying the defendants' motion for partial summary judgment of non-infringement, Dkt. No. 394, the Court also indicated that in light of the parties' positions expressed in the briefing on that motion, it might be necessary to conduct further claim construction of the "treating" limitations found in several of the claims of the patents in suit.

[3] It is not clear to the Court whether the limitation on the stipulation to infringement under section 271(e)(2) might make the stipulation less than fully effective to remove the issue of infringement from the case. The Court understands Allergan's position to be that, absent an at-risk launch by one or more of the defendants, Allergan's proof will be the same for its claims under section 271(a), (b), and (c) as for its claims under section 271(e)(2). The Court also understands that the defendants did not intend to limit the scope of their stipulation so that fails to remove the issue of infringement under section 271(a), (b), and (c) from the trial. However, the scope of the stipulation, as currently framed, leaves that matter unresolved.

stipulating to infringement under that claim construction to put the case in a posture for an immediate appeal, see, e.g., Augme Techs., Inc. v. Yahoo! Inc., 755 F.3d 1326 (Fed. Cir. 2014); Seachange Int'l, Inc. v. C-COR, Inc., 413 F.3d 1361 (Fed. Cir. 2005); Durel Corp. v. Osram Sylvania, 256 F.3d 1298 (Fed. Cir. 2001).

In the former category of cases, the issue of infringement is removed from the case for good, allowing the district court and the court of appeals to focus exclusively on the issue of invalidity. Because the invalidity issue is typically discrete, factually and legally, from the issue of infringement, the stipulation procedure ordinarily results in a clear gain in efficiency for the courts and the parties.

In the second category of cases, the benefits of the stipulation process are not so self-evident. In those cases, the parties are able to obtain what amounts to interlocutory review of a claim construction without having to obtain permission from the appellate court, as would be required if the parties sought formal interlocutory review under 28 U.S.C. § 1292(c). And while the stipulation process may be efficient in some cases, it sometimes has significant costs. First, the district court is denied the opportunity to shape its claim construction in light of information obtained in the course of the trial. Second, and relatedly, the appellate court does not have the benefit of a factual context in which to consider the claim construction issue. See Jang v. Boston Sci. Corp., 532 F.3d 1330, 1337-38 (Fed. Cir. 2008); Lava Trading, Inc. v. Sonic Trading Mgmt., LLC, 445 F.3d 1348, 1350 (Fed. Cir. 2006); Superior Indus., Inc. v. Masaba, Inc., 553 F. App'x 986 (Fed. Cir. 2014). Third, the appellate court is denied the opportunity to decide whether, in light of the evidence at trial, any claim construction error would not have affected the judgment. Jang, 532 F.3d at 1336-37.

Notwithstanding those concerns, such stipulations have been approved by district courts, and appeals predicated on such stipulations have frequently been permitted. In this case, however, there is uncertainty as to the scope of the stipulation and as to the ultimate claim construction. As a result, the offered stipulation in its current form has the potential to make the proceedings—and particularly any appeal that may be taken from the ultimate judgment—more complicated, not less.

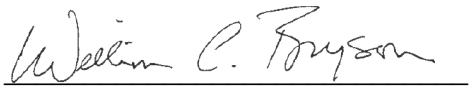
During an August 23, 2017, telephonic conference at which the Court heard from the parties regarding the pending motions, counsel for the defendants stated that the defendants' intention was to take the issue of infringement out of the case and not to do so in a qualified manner that would fail to achieve the purpose of the defendants' stipulation. The Court urged the parties to discuss the possibility of a stipulation that would not have the problems that Allergan complained of (and the Court found to be present) in the defendants' initial offered stipulation. The parties agreed to do so and to advise the Court of the outcome of their discussions.

As for the order of proof at trial, Allergan intends to offer some background evidence at trial regarding the development of Restasis through the witnesses who are now scheduled to testify at the beginning of the trial. Having that evidence come in at the beginning of the trial is more logical than postponing it until after the defendants have presented their case-in-chief on invalidity. Moreover, the convenience of the third-party witnesses is a factor that bears on the Court's decision as to the order of proof at trial. The defendants made their proposal to modify the order of proof only ten days before the beginning of the trial. By then, it is understandable that Allergan's witnesses had made arrangements to be present at the beginning of the trial, and that altering the order of proof could be highly inconvenient for them.

When infringement has been conceded, courts have on occasion acquiesced in the request of the accused infringer to present its case first at trial. In several of those instances, however, the courts have allowed the patentee to present background information at the outset before the accused infringer begins its invalidity challenge. See Novartis Pharms. Corp. v. Teva Pharms. USA, Inc., No. 05-cv-1887, 2009 WL 3334850, at *2 (D.N.J. Oct. 14, 2009); Pfizer Inc. v. Ivax Pharms., Inc., No. Civ. A 07-cv-174, 2009 WL 2905454, at *9 (D.N.J. Sept. 9, 2009); Merck Sharp & Dohme Pharms., SRL v. Teva Pharms. USA, Inc., No. 07-1596 (D.N.J. Nov. 5, 2008). That sequence seems fair to the Court in this case, particularly in light of Allergan's having organized the appearance of its background witnesses around the assumption that it would go first at trial. The Court therefore will not accept the current version of defendants' stipulation as a basis for treating the issue of infringement as being removed from the case and will deny the defendants' motion to alter the order of proof.

IT IS SO ORDERED.

SIGNED this 25th day of August, 2017.



WILLIAM C. BRYSON
UNITED STATES CIRCUIT JUDGE